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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

ROB BECERRA, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

v.

ZOSANO PHARMA CORPORATION, STEVEN LO, JOHN P. WALKER, and KONSTANTINOS ALATARIS,

Defendants.

Case No:

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Plaintiff Rob Becerra ("Plaintiff"), individually and on behalf of all others similarly situated, by and through Plaintiff's attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, the investigation conducted by Plaintiff's counsel, which includes without limitation: (a) review and analysis of regulatory filings made by Zosano Pharma Corporation ("Zosano" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Zosano; and (c) review of other publicly available information concerning Zosano.

NATURE OF THE ACTION

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Zosano securities between February 13, 2017 and September 30, 2020, inclusive (the "Class Period"), seeking to pursue claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Zosano is a clinical stage pharmaceutical company. Its proprietary intracutaneous delivery system purports to offer rapid absorption of drug, consistent drug delivery, improved ease of use, and room-temperature stability. Its intracutaneous patch consists of an array of titanium microneedles that is coated with Zosano's proprietary formulation of a previously approved drug that is attached to an adhesive patch. The patch purports to offer rapid and consistent delivery of the drug via the microneedles that penetrate the skin, resulting in dissolution and absorption of the drug.

3. Zosano's lead product candidate is Qtrypta (M207), a formulation of zolmitriptan coated onto the Company's microneedle patch. The Company's pivotal efficacy trial, called ZOTRIP, began in July 2016. In December 2019, Zosano submitted its New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") seeking regulatory approval for Qtrypta.

4. On September 30, 2020, after the market closed, Zosano disclosed receipt of a discipline review letter ("DRL") from the FDA regarding its NDA for Qtrypta and stated that approval was not likely. According to the Company's press release, the FDA "raised questions regarding unexpected high plasma concentrations of zolmitriptan observed in five study subjects from two pharmacokinetic studies and how the data from these subjects affect the overall clinical pharmacology section of the application." The FDA also "raised questions regarding differences in zolmitriptan exposures observed between subjects receiving different lots of Qtrypta in the company's clinical trials."

5. On this news, the Company's share[1] price fell $0.92 per share, or 56.79%, to close at $0.70 per share on October 1, 2020, on unusually heavy trading volume.

6. On October 21, 2020, Zosano disclosed receipt of a Complete Response Letter ("CRL") from the FDA. As a result of the previously identified deficiencies, the FDA recommended that Zosano conduct a repeat bioequivalence study between three of the lots used during development.

7. On this news, the Company's share price fell $0.171 per share, or 27.8%, to close at $0.444 per share on October 21, 2020, on unusually heavy trading volume.

8. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors that: (i) the Company's clinical results reflected differences in zolmitriptan exposures observed between subjects receiving different lots; (ii) pharmocokinetic studies submitted in connection with the Company's NDA included patients exhibiting unexpected high plasma concentrations of zolmitriptan; (iii) as a result of the foregoing differences among patient results, the FDA was reasonably likely to require further

[1] The Company effected a 1-for-20 reverse stock split on January 25, 2018. All share prices herein reflect the post-split price.

studies to support regulatory approval of Qtrypta; (iv) as a result, regulatory approval of Qtrypta was reasonably likely to be delayed; and (v) as a result of the foregoing, Defendants' public statements were materially false and misleading at all relevant times.

9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

10. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

12. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are located in this District.

13. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the U.S. mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

14. Plaintiff, as set forth in the accompanying Certification, incorporated by reference herein, purchased or otherwise acquired Zosano securities during the Class Period, and suffered

damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

15. Defendant Zosano is a Delaware corporation with principal executive offices located in Fremont, California. Zosano's common stock trades in an efficient market on the NASDAQ exchange ("NASDAQ") under the symbol "ZSAN."

16. Defendant Steven Lo ("Lo") has been the Chief Executive Officer ("CEO") of the Company since October 2019.

17. Defendant John P. Walker ("Walker") was the CEO of the Company from May 2017 to October 2019.

18. Defendant Defendant Konstantinos Alataris ("Alataris") was the CEO of the Company from 2016 to May 2017.

19. Defendants Lo, Walker, and Alataris (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

20. Zosano is a clinical stage pharmaceutical company. Its proprietary intracutaneous delivery system purports to offer rapid absorption of drug, consistent drug delivery, improved ease of use, and room-temperature stability. The Company's intracutaneous patch consists of an array of titanium microneedles that is coated with Zosano's proprietary formulation of a previously approved drug that is attached to an adhesive patch. The patch purports to offer rapid and consistent delivery of the drug via the microneedles that penetrate the skin, resulting in dissolution and absorption of the drug.

21. Zosano's lead product candidate is Qtrypta (M207), a formulation of zolmitriptan coated onto the Company's microneedle patch used for the treatment of migraines. The Company's pivotal efficacy trial of M207, called ZOTRIP, began in July 2016.

Materially False and Misleading Statements Issued During the Class Period

22. The Class Period begins on February 13, 2017. On that day, Zosano announced the results of its clinical study regarding M207. In a press release, the Company stated, in relevant part:

> Zosano . . . announces that its lead product candidate, M207, achieved both co-primary endpoints of pain freedom and most bothersome symptom freedom at 2 hours in the recently completed ZOTRIP trial. The ZOTRIP pivotal efficacy study was a multicenter, double-blind, randomized, placebo-controlled, dose-ranging trial comparing three doses (1.0mg, 1.9mg and 3.8mg) of M207, a novel transdermal therapeutic, to placebo for a single migraine attack. A total of 589 subjects were enrolled at 36 sites across the US. The 3.8mg dose achieved significance in the secondary endpoints of pain freedom at 45 minutes and 1 hour and showed durability of effect on pain freedom at 24 and 48 hours. Additionally, M207 was not associated with any Serious Adverse Events (SAEs).
>
> The 3.8mg dose of M207 achieved statistical significance for both co-primary endpoints at two hours[.]
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> * * *
>
> Furthermore, secondary endpoints measuring pain freedom at additional time points for the 3.8mg dose of M207 showed M207 superior to placebo with a nominal p-value less than 0.05[.]

* * *

> Overall, higher pain freedom rates were achieved on all doses after 60 minutes over placebo. While the 1.0mg and 1.9mg doses of M207 produced p-values less than 0.05 in pain freedom at two hours, they did not produce a p-value below 0.05 for the coprimary endpoint of freedom from most bothersome symptom at two hours.
>
> "ZOTRIP was designed to be a dose-ranging study, as well as a registration study. We are very pleased by the results for the 3.8mg dose, and look forward to continuing the development of M207 towards filing an NDA and working to bring this novel therapy to patients suffering from the incapacitating effects of migraines," said Konstantinos Alataris PhD, President and Chief Executive Officer of Zosano.

23. On March 1, 2017, Zosano filed its annual report on Form 10-K for the period ended December 31, 2016 (the "2016 10-K"). Therein, the Company stated, regarding the development and regulatory approval for M207:

> ***The long-term safety study for M207 is an important next step in the development of M207. If we cannot raise capital, manufacture supply for the safety study, launch the safety study in a timely manner, enroll subjects, or produce results that satisfy FDA requirements, the regulatory approval process could be delayed and our business could be adversely affected.***
>
> After receiving positive results from our ZOTRIP Phase 2/3 efficacy trial of M207, the next step in the regulatory approval process is to prepare, initiate, and complete a long-term safety study. We plan to initiate this study in the second half of 2017. To conduct this safety study, we will need to raise additional capital to fund the manufacture sufficient supply of M207, launch the study, and enroll subjects in the study. There are no assurances that such additional capital will be available to us on terms that are favorable to us or our existing stockholders or at all. The study will also need to produce results that satisfy FDA requirements. Any failure or setback in completing any of these required steps could require us to delay, limit, reduce or terminate our development of M207. Also, even though we have discussed our development strategy with the FDA on our M207 program and received feedback from the FDA about the size and the length of the safety study, the FDA may decide to expand on the requirements that have already been provided to us, which would further delay the regulatory approval process.

24. On May 9, 2017, Zosano announced its first quarter 2017 financial results in a press release that also stated, in relevant part:

> "The first quarter saw our lead product candidate meet both co-primary endpoints in ZOTRIP, our pivotal efficacy study of M207 as an acute treatment for migraine. In addition, the company completed a follow-on offering that resulted in $29.3 million in gross proceeds earmarked for advancing M207 towards FDA approval. These two

important accomplishments are a result of the commitment and capabilities of Zosano's management team and gives me great confidence in our ability to continue to meet the strategic milestones established by the company."

"The pivotal study results importantly validate our technology platform, and, if approved by the FDA, point to M207's positioning as an acute treatment for migraine sufferers that is differentiated from what is currently available. I look forward to working with the team at Zosano and to bringing this exciting new drug to market," commented John P. Walker, Interim Chief Executive Officer.

* * *

Pivotal Study Results / Status

In February, the Company announced statistically significant results from the ZOTRIP trial, which demonstrated that the 3.8mg dose of M207 met both co-primary endpoints, achieving pain freedom and most bothersome symptom freedom at 2 hours. The 3.8mg dose achieved a p value of <0.05 in the secondary endpoints of pain freedom at 45 minutes and 1 hour, and showed durability of effect on pain freedom to 24 and 48 hours. These results demonstrated that M207 not only provided fast onset but also a durability of effect, up to 2 days and hence freedom from recurrence of migraine. Additionally, M207 demonstrated a similar safety profile as other triptans and no Serious Adverse Events (SAEs) were reported in the trial.

The FDA has indicated that a single, positive, pivotal efficacy study, in addition to a safety study of M207, will be sufficient to file for approval under a 505(b)(2) pathway. The Company plans to initiate the safety study in the second half of 2017.

25. On June 26, 2017, Zosano announced that it completed Phase 2 meetings with the FDA regarding Zotrip. Specifically, in a press release, the Company stated, in relevant part:

Confirmation of previously announced design of Long-term Safety Study

Recently completed ZOTRIP study acknowledged sufficient for NDA filing

CMC development strategy confirmed adequate for registration

[. . . .] Zosano . . . today announced receipt of final minutes from recent End of Phase 2 meetings with the U.S. Food and Drug Administration (FDA). The focus of this meeting was to confirm three key elements to the continued development of Zosano's lead program, M207 as an acute treatment for migraine:

- Confirmation of a single, positive Efficacy Study Sufficient for NDA filing — Zosano received confirmation that a single efficacy study, our recently completed ZOTRIP trial, is sufficient to support an NDA filing for M207. Final

determination of whether sufficient efficacy has been achieved remains subject to an NDA submission and formal FDA review of the data from the ZOTRIP trial.

- Design of Long-term Safety Study — FDA confirmed the previously announced design of the Long-term Safety Study as sufficient to support an NDA filing for M207. The trial will evaluate the safety of repeat dosing of M207 in migraine patients, evaluating 150 patients to six months and 50 patients to a year. It is anticipated that patients will use M207 a minimum of twice per month. The primary emphasis will be on confirming skin tolerability during a year of dosing.

- Chemistry, Manufacturing and Controls — In a separate, concurrent communication, Zosano presented its proposed CMC development plan to the FDA. The FDA concurred that the development strategy, which conforms to relevant regulatory guidelines, appears adequate for registration of M207. CMC approval remains subject to NDA submission and FDA formal review and successful site inspections.

"We are pleased with the collaborative end-of-Phase 2 meetings with FDA that enabled us to receive detailed guidance regarding the further development of M207 and advancing towards an NDA filing," said Don Kellerman, Zosano's Vice President, Clinical Development and Medical Affairs. "This meeting represents the completion of another important milestone for M207, and we look forward to initiating our Long-term Safety Study in the third quarter of 2017, as previously announced."

M207 is designed to rapidly deliver zolmitriptan during a migraine attack utilizing Zosano's proprietary Adhesive Dermally-Applied Microarray, or ADAM technology. Zosano's ADAM technology consists of titanium microprojections coated with drug, and in the case of M207, our formulation of zolmitriptan. Our ADAM technology delivers zolmitriptan by abrading the stratum corneum and allowing drug to be absorbed into the microcapillary system of the skin.

As previously reported, the 3.8mg dose of M207 achieved both co-primary endpoints of pain freedom and most bothersome symptom freedom at 2 hours. In addition, the 3.8mg dose achieved significance in the secondary endpoints of pain freedom at 45 minutes and 1 hour and showed durability of effect on pain freedom at 24 and 48 hours. 41.5% of the patients treated with the 3.8mg dose of M207 achieved pain freedom at 2 hours, and the effect also appeared to be durable, with 31.7% and 26.8% of patients achieving sustained pain freedom from 2-24 hours and 2-48 hours, respectively. In post-hoc analyses, M207 also demonstrated efficacy in traditionally difficult to treat established migraine headaches, as evidenced by a nearly identical therapeutic gain in those who treated prior to and after 2 hours. Additionally, 44% of patients who awoke with their migraine headache were pain free at 2 hours. Patients in this trial were instructed not to treat until their headache reached moderate to severe intensity, and the mean time from headache onset to treatment was almost 5 hours. M207 was well-tolerated with no SAEs. Overall, 13 subjects (3.9%) reported pain at the application site; application site pain was reported as mild in all but 3 subjects. The most frequently reported adverse event was redness at

the application site (18.3% of subjects). All cases of redness resolved. Additionally, 5 (1.5%) patients across M207-treated groups reported dizziness vs 0% on placebo.

26. On March 12, 2018, the Company filed its annual report on Form 10-K with the SEC for the period ended December 31, 2017 (the "2017 10-K"). Regarding regulatory approval of M207, the Company stated, in relevant part:

> ***If the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful***.
>
> We intend to seek FDA approval through the 505(b)(2) regulatory pathway for each of our product candidates described in this Annual Report on Form 10-K. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act ("FDCA"). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant.
>
> If the FDA does not allow us or any partner with which we collaborate to pursue the 505(b)(2) regulatory pathway for our product candidates, we or they may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, we or they will need to successfully complete additional Phase 2 and/or Phase 3 clinical trials and submit to the FDA for approval one or more NDAs in order to obtain FDA approval to market each of our product candidates. The time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. The conduct of later-stage clinical trials and the submission of a successful NDA is a complicated process. To date, we have conducted only one Phase 2/3 clinical trial and have initiated a long-term safety study of M207, we have limited experience in preparing and submitting regulatory filings, and we have not previously submitted an NDA for any product candidate. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to an NDA submission for M207 or for any other product candidates we may develop in the future.
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> Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite approvals for commercialization of such product candidate.

> In addition, our competitors may file petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

27. On October 23, 2018, Zosano announced that "150 evaluable subjects have completed their six month visit in the M207-ADAM study . . . , a long-term, open-label safety study for the acute treatment of migraine." The press release stated, in relevant part:

> No unexpected safety signals have been identified during the first six months of the trial and there have been no study drug related serious adverse events. The total number of investigator reported adverse events, with 4,000 applications to date, is 625 of which 232 are reported as skin site reactions and 120 triptan related adverse events. The remainder of the adverse events (273) include nasal congestion, gastrointestinal disorders, appetite suppression, respiratory tract infections and insomnia, among others. Efficacy parameters, while observational in the context of this open label safety study, continue to remain similar to the data from the pivotal ZOTRIP trial. The rate of pain freedom at two hours following patch application is approximately 43% and most bothersome symptom freedom is approximately 68%, while pain relief at two hours post treatment is reported at 81% of migraine attacks treated.

28. On February 21, 2019, Zosano announced the results of its long-term safety study for Qtrypta. In a press release, the Company stated, in relevant part:

- Long-term one-year dosing reaffirmed well-tolerated safety profile
- Qtrypta showed robust and rapid relief of migraine pain, an effect that was consistent throughout the chronic treatment period
- NDA submission expected in Q4 2019 for the first intracutaneous delivery system

> [. . . .] Zosano . . . today announced the completion of the second and final goal of the long-term safety study for Qtrypta, in which patients treated migraine attacks over a one year period. The long-term data generated in this trial reinforced the well-tolerated safety profile and strong efficacy results previously reported in the six-month dosing portion of this safety study and in the randomized Phase 2/3 ZOTRIP pivotal study. Throughout the clinical program, over 5,800 migraine attacks have been treated with Qtrypta to date.
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> * * *
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> The Qtrypta long-term safety trial is an open-label study evaluating the safety of the 3.8 mg dose of intracutaneous zolmitriptan in adults with migraine who have historically experienced at least 2 migraine attacks per month. There were no maximum treatment

limits. The study evaluated over 150 adults with migraine disease for six months, and more than 50 patients for a year at 31 sites in the U.S.

Of more than 5,800 migraines treated, investigators reported 832 adverse events, of which 298 were reported as application site reactions and 161 were reported as triptan related adverse events.

Observational efficacy parameters continued to demonstrate a rate of pain freedom at two hours following patch application of approximately 44% and most bothersome symptom freedom of approximately 68%, while pain relief at two hours was reported at 81% of migraine attacks treated.

29. On March 25, 2019, the Company filed its annual report on Form 10-K for the period ended December 31, 2018 (the "2018 10-K"). Regarding clinical results and regulatory approval of M207, Zosano stated, in relevant part:

The long-term safety study for Qtrypta™ (M207) is an important step in the development of Qtrypta™ (M207). If we cannot produce results that satisfy FDA requirements, the regulatory approval process could be delayed, and our business could be adversely affected.

In February 2019, we announced the completion of the final phase of our long-term safety study where more than 50 evaluable subjects were treated for a year. This long-term safety study will need to produce results that satisfy FDA requirements. If the results do not satisfy the FDA's requirements it could require us to delay, limit, reduce or terminate our development of Qtrypta™ (M207). Also, even though we have discussed our development strategy with the FDA on our Qtrypta™ (M207) program and received feedback from the FDA about the size and the length of the safety study, the FDA may decide to expand on the requirements that have already been provided to us, which would further delay the regulatory approval process and require additional clinical work.

If the FDA does not conclude that our product candidate satisfies the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of our product candidate under Section 505(b)(2) are not as we expect, the approval pathway for our product candidate will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for our product candidate described in this Annual Report on Form 10-K. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant.

> If the FDA does not allow us or any partner with which we collaborate to pursue the 505(b)(2) regulatory pathway for our product candidate, we or they may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, we or they will need to successfully complete additional Phase 2 and/or Phase 3 clinical trials and submit to the FDA for approval one or more NDAs in order to obtain FDA approval to market our product candidate. The time and financial resources required to obtain FDA approval for our product candidate would likely substantially increase. The conduct of later-stage clinical trials and the submission of a successful NDA is a complicated process. To date, we have conducted only one Phase 2/3 clinical trial and have initiated a long-term safety study of Qtrypta™ (M207), we have limited experience in preparing and submitting regulatory filings, and we have not previously submitted an NDA for any product candidate. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to an NDA submission for Qtrypta™ (M207) or for any other product candidate we may develop in the future.
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> Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidate, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite approvals for commercialization of such product candidate.
>
> In addition, our competitors may file petitions with the FDA in an attempt to persuade the FDA that our product candidate, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

30. On November 13, 2019, Zosano announced that it had completed pre-NDA meetings with the FDA for Qtrypta, stating in relevant part:

> Zosano . . . today announced that it has received minutes from pre- New Drug Application ("NDA") meetings with the Food and Drug Administration ("FDA") for the acute treatment of migraine for Qtrypta. ***The purpose of the meetings was to confirm the completion of all requisite studies, as well as the proposed clinical, non-clinical, and chemistry, manufacturing, and controls ("CMC") content and format of the company's NDA submission, which the company expects to make in December 2019.***
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> ***"We are encouraged by the pre-NDA minutes received from FDA after our collaborative meetings.*** This is an important milestone as we head into the final stages of completion of the NDA," said Hayley Lewis, Senior Vice President, Operations. "These minutes reflect discussions made between Zosano and FDA on the format and content of the NDA to help ensure all elements of submission are met."
>
> The company was granted two separate pre-NDA meetings to discuss the development program. A face to face meeting was held with the FDA in September to discuss the

> nonclinical and clinical portions of the program. ***A second pre-NDA meeting request was granted to discuss CMC, and FDA recently provided its written responses to the company's questions in lieu of holding an in-person meeting.*** Based on the feedback from the FDA, the company believes the information included in its planned NDA will be sufficient for the FDA to file the NDA for substantive review.

31. On November 14, 2019, Zosano announced its third quarter 2019 financial results and provided a corporate update. In a press release, the Company stated, in relevant part:

> "These next twelve months will be transformational for Zosano," said Steven Lo, president and CEO of Zosano. "We are finalizing our New Drug Application for Qtrypta for the acute treatment of migraine, which we expect to file with the FDA by the end of the year. If approved, Qtrypta would be the first transdermal therapy for migraine, and we believe would represent a significant advance in the treatment options available to patients. ***Our extensive clinical data demonstrate that Qtrypta provides fast-acting and sustained pain freedom with less of the side effects typically experienced with other therapies in this class.*** Given the debilitating and prevalent nature of migraines, we are inspired by the need to better serve these patients."

32. On December 23, 2019, Zosano announced that it had submitted its NDA for Qtrypta to the FDA, stating in a press release:

> "Our NDA submission represents a significant milestone for Zosano and a culmination of our efforts to make Qtrypta available to patients who suffer from migraine. In clinical trials, Qtrypta demonstrated robust freedom from pain and most bothersome symptom, rapid and sustained pain relief, and was well tolerated," said Steven Lo, president and chief executive officer of Zosano. "Qtrypta is the first NDA to be submitted to the FDA for a pharmaceutical microneedle application, and we look forward to working with the FDA during the review process. If successful, the approval would signal the validity of this product as a convenient, non-oral therapy for acute migraine sufferers, in addition to providing important validation of our delivery technology itself. We believe that Qtrypta, if approved, can make an important difference in the lives of patients who require acute treatment options for their migraine."
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> Based on Zosano's NDA submission on Friday, December 20, 2019, the company expects to receive notification from the FDA confirming whether the submission was accepted for filing for substantive review in March 2020.
>
> The submission is supported by the results of the ZOTRIP pivotal Phase 2/3 clinical study, in which 41.5% of patients treated with the 3.8 mg dose of Qtrypta achieved pain freedom at 2 hours and 68.3% reported freedom from most bothersome symptom at 2 hours, both of which were co-primary endpoints. Additionally, 80.5% of patients reported pain relief at 2 hours, a secondary endpoint. The results of the study were published in Cephalalgia in October 2017.

> A post-hoc analysis showing that Qtrypta reduced pain in subjects with difficult to treat migraines was published in Headache: The Journal of Head and Face Pain in February 2019.
>
> Additionally, in the Phase 3 safety study, the most frequently reported adverse events were redness and swelling at the application site. Of these, 95% were reported as mild, and more than 80% resolved within 48 hours. Less than 2% of patients reported triptan-like neurological side effects typically found in the class, such as dizziness and paresthesia.

33. On March 4, 2020, Zosano announced that the FDA had accepted the NDA for review and that the goal date for the completion of the FDA's review was October 20, 2020. In a press release, the Company further stated:

> The NDA is supported by the clinical results of the ZOTRIP pivotal Phase 2/3 clinical study, which evaluated the efficacy, safety and tolerability of Qtrypta™ compared to placebo. A total of 41.5% of patients treated with the 3.8 mg dose of Qtrypta™ achieved pain freedom at 2 hours and 68.3% reported freedom from most bothersome symptom also at 2 hours, both of which were co-primary endpoints. Additionally, 80.5% of patients reported pain relief at 2 hours, a secondary endpoint. The results of the study were published in Cephalalgia in October 2017.
>
> A post-hoc analysis showing that Qtrypta™ reduced pain in subjects with difficult to treat migraine attacks was published in Headache: The Journal of Head and Face Pain in February 2019.
>
> Additionally, in the Phase 3 long term safety study, the most frequently reported adverse event was redness at the application site. Of these adverse events, 95% were reported as mild, and more than 80% resolved within 48 hours. Less than 2% of patients reported triptan-like neurological side effects typically found in the class, such as dizziness and paresthesia.

34. On March 13, 2020, the Company filed its annual report on Form 10-K for the period ended December 31, 2019 (the "2019 10-K"). Regarding clinical results and regulatory approval of M207, the 2019 10-K was substantially similar to the 2018 10-K.

35. The above statements identified in ¶¶ 22-34 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors that: (i) the Company's clinical results reflected differences in zolmitriptan exposures observed between subjects receiving different lots; (ii)

pharmocokinetic studies submitted in connection with the Company's NDA included patients exhibiting unexpected high plasma concentrations of zolmitriptan; (iii) as a result of the foregoing differences among patient results, the FDA was reasonably likely to require further studies to support regulatory approval of Qtrypta; (iv) as a result, regulatory approval of Qtrypta was reasonably likely to be delayed; and (v) as a result of the foregoing, Defendants' public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

36. On September 30, 2020, after the market closed, Zosano disclosed receipt of a DRL from the FDA regarding its NDA for Qtrypta and stated that approval was not likely due to certain concerns identified by the FDA. Specifically, the Company's press release stated, in relevant part:

> The DRL described two concerns with respect to the clinical pharmacology section of the NDA. First, the FDA raised questions regarding unexpected high plasma concentrations of zolmitriptan observed in five study subjects from two pharmacokinetic studies and how the data from these subjects affect the overall clinical pharmacology section of the application. Second, the FDA raised questions regarding differences in zolmitriptan exposures observed between subjects receiving different lots of Qtrypta in the company's clinical trials.
>
> Although a DRL reflects preliminary comments that are subject to change, and does not reflect the FDA's final decision on the NDA, approval of Qtrypta by the Prescription Drug User Fee Act goal date of October 20, 2020 is not expected given the letter.

37. On this news, the Company's share price fell $0.92 per share, or 56.79%, to close at $0.70 per share on October 1, 2020, on unusually heavy trading volume.

38. Then, on October 21, 2020, Zosano disclosed receipt of a CRL from the FDA. As a result of the previously identified deficiencies, the DFA recommended that Zosano conduct a repeat bioequivalence study between three of the lots used during development.

39. On this news, the Company's share price fell $0.171 per share, or 27.8%, to close at $0.444 per share on October 21, 2020, on unusually heavy trading volume.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

40. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Zosano securities during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

41. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Zosano's common shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Zosano common stock were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Zosano or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

42. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

43. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

44. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Zosano; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

45. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

46. The market for Zosano's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements, and/or failures to disclose, alleged herein, Zosano's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Zosano's securities relying upon the integrity of the market price of the Company's securities and market information relating to Zosano, and have been damaged thereby.

47. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Zosano's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because

they failed to disclose material adverse information and/or misrepresented the truth about Zosano's business, operations, and prospects as alleged herein.

48. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Zosano's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

49. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

50. During the Class Period, Plaintiff and the Class purchased Zosano's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

51. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false

and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Zosano, their control over, and/or receipt and/or modification of Zosano's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Zosano, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE
(FRAUD-ON-THE-MARKET DOCTRINE)

52. The market for Zosano's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Zosano's securities traded at artificially inflated prices during the Class Period. On February 17, 2017, the Company's share price closed at a Class Period high of $62.40 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Zosano's securities and market information relating to Zosano, and have been damaged thereby.

53. During the Class Period, the artificial inflation of Zosano's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Zosano's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Zosano and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when

disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

54. At all relevant times, the market for Zosano's securities was an efficient market for the following reasons, among others:

(a) Zosano shares met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Zosano filed periodic public reports with the SEC and/or the NASDAQ;

(c) Zosano regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Zosano was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

55. As a result of the foregoing, the market for Zosano's securities promptly digested current information regarding Zosano from all publicly available sources and reflected such information in Zosano's share price. Under these circumstances, all purchasers of Zosano's securities during the Class Period suffered similar injury through their purchase of Zosano's securities at artificially inflated prices and a presumption of reliance applies.

56. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

57. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Zosano who knew that the statement was false when made.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

58. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

59. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Zosano's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

60. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Zosano's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

61. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Zosano's financial well-being and prospects, as specified herein.

62. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Zosano's value and performance and

continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Zosano and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

63. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

64. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Zosano's financial wellbeing and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or

misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, these defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

65. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Zosano's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by these defendants during the Class Period, Plaintiff and the other members of the Class acquired Zosano's securities during the Class Period at artificially high prices and were damaged thereby.

66. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Zosano was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Zosano securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

67. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

68. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

69. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

70. The Individual Defendants acted as controlling persons of Zosano within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

71. In particular, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

72. As set forth above, Defendants each violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by their acts and/or omissions as alleged in this Complaint. By

virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: November 6, 2020

Respectfully submitted,

POMERANTZ LLP

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